

STANDARD MEDICARE PART B MANAGEMENT

KRYSTEXXA (pegloticase)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Krystexxa is indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

Limitations of Use

Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Chronic gout

Authorization of 12 months may be granted for treatment of chronic gout when EITHER of the following criteria are met:

- A. The member is refractory to conventional therapy (e.g., allopurinol, febuxostat).
- B. The member has a clinical reason to avoid therapy with all conventional therapies.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with Krystexxa.
- B. Krystexxa is being used to treat an indication enumerated in Section II.
- C. The member is receiving benefit from therapy.

IV. REFERENCES

1. Krystexxa [package insert]. Lake Forest, IL: Horizon Therapeutics USA, Inc.; January 2020.